IRB "Boilerplate" Language for Alteration of Informed Consent Process

(for use with IRB minutes, but could be "tweaked" for use in reports)

1. For waiver of 45 CFR 46.116(a)(4) (the alternative procedures required element):

   In accordance with 45 CFR 46.116(d), the Board voted to approve (?-?) an alteration of the informed consent process by waiving the required element of informed consent described in 45 CFR 46.116(a)(4) regarding appropriate alternative procedures that may be available to participants. The Board determined that the study would pose no greater than minimal risk to participants and that omission of this required element from the consent process would not adversely affect the rights or welfare of the subjects. In fact, for this type of research, the Board determined that the only appropriate alternative available to the subject would be to not participate in the study. Members felt that including such a statement could adversely affect the welfare of subjects by causing confusion and unnecessary concern, and, although investigators could simply include a statement to the effect that the "only alternative is to not participate," it seemed illogical to members, and they believed it could possibly jeopardize the credibility of the study. The Board, therefore, determined that it was not practicable to include the statement. The Board also decided that the fourth criterion for altering the informed consent process did not apply to this situation.

2. For waiver of 45 CFR 46.116(a)(7) (the research-related injury contact required element):

   In accordance with 45 CFR 46.116(d), the Board voted to approve (?-?) an alteration of the informed consent process by waiving the required element of informed consent described in 45 CFR 46.116(a)(7) regarding the inclusion of a contact person for research-related injury. The Board determined that the study would pose no greater than minimal risk to participants and that omission of this required element from the consent process would not adversely affect the rights or welfare of the subjects. The Board noted that participants are provided with information about whom to contact if they have questions about the research or if they have questions about their rights as research subjects. However, for this type of research, the Board determined that including such a statement could adversely affect the welfare of subjects by raising unnecessary concern about physical or other injury that would not occur. Members felt that although investigators could simply include a contact person for research-related injury, it seemed illogical to members, they believed it could possibly jeopardize the credibility of the study, and they felt it may be more harmful than beneficial to subjects. The Board, therefore, determined that it was not practicable to include the statement. The Board also decided that the fourth criterion for altering the informed consent process did not apply to this situation.

3. For waiver of 45 CFR 46.116(a)(8) (the "no penalty or loss of benefits" required element):

   In accordance with 45 CFR 46.116(d), the Board voted to approve (?-?) an alteration of the informed consent process by waiving the required element of informed consent described in

45 CFR 46.116(a)(8) regarding including the statement that subjects may refuse to participate or may discontinue participation with no penalty or loss of benefits to which the subject is otherwise entitled. The Board determined that the study would pose no greater than minimal risk to participants and that omission of this required element from the consent process would not adversely affect the rights or welfare of the subjects. The Board felt that for this type research, a statement regarding "loss of benefits" was not relevant. In fact, the Board has been apprized that in some past situations, including this statement has led subjects to believe that the federal government is interfering with their benefits, resulting in mistrust of those involved in the study. The Board, therefore, determined that it was not practicable to include the statement. The Board also decided that the fourth criterion for altering the informed consent process did not apply to this situation.